UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO PRECLUDE DEFENSE EXPERT JASON O. CLEVENGER, PH.D., FROM OFFERING CLASS CERTIFICATION OPINIONS

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Pursuant to Federal Rules of Evidence 702, Defendants Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma LLC (collectively, "Aurobindo") submit this memorandum of law in opposition to Plaintiffs' *Daubert* Motion to Preclude Defense Expert Jason O. Clevenger, Ph.D. from Offering Class Certification Opinions ("Motion" or "Mot."), ECF No. 2047.

I. INTRODUCTION

Plaintiffs' Motion mischaracterizes and distorts the analysis and opinions of Dr. Clevenger, a Ph.D. chemist with substantial non-litigation pharmaceutical experience. Plaintiffs' challenges fail when Dr. Clevenger's actual opinions are examined in light of the evidence. At most, Plaintiffs raise potential issues for cross-examination, not substantive bases to exclude Dr. Clevenger's well-founded opinions based on appropriate scientific analysis. Accordingly, Plaintiffs' Motion must be denied.

II. LEGAL STANDARD

"[C]ourts serve as gatekeepers for expert witness testimony. A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if, *inter alia*, the testimony is the product of reliable principles and methods and the expert has reliably applied the principles and methods to the facts of the case." *In re Zoloft (Sertaline Hydrochloriade) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017) (alterations

accepted and internal quotation marks omitted). The Court must review "[b]oth an expert's methodology and the application of that methodology . . . for reliability." *Id.* However, "an expert should only be excluded if the flaw is large enough that the expert lacks the good grounds for his or her conclusions." *Id.* at 792-93 (citations and internal quotation marks omitted). As this Court has previously held, the appropriate means for challenging other perceived deficiencies in an expert's opinion is [redacted]

III. ARGUMENT

A. Dr. Clevenger Properly Opined on Compliance with the USP Monograph.

Plaintiffs distort the substance of Dr. Clevenger's testimony and then anchor their arguments to those distortions—such a silly attempt to exclude Dr. Clevenger is worth no serious consideration from this Court. Plaintiffs attempt to wrap together Dr. Clevenger's separate but related opinions on pharmaceutical equivalence and bioequivalence. Without any explanation, plaintiffs assert that Dr. Clevenger conflates the two. Mot., 1. Not true. In fact, Dr. Clevenger *distinguishes* between them and opines that Aurobindo's VCD satisfied *both* standards regardless of the

[1] Exhibit 6 is attached to "Defendants' Memorandum of Law in Opposition to Plaintiffs' *Daubert* Motion to Preclude Defense Expert William J. Lambert, PH.D., from Offering Class Certification Opinions" filed simultaneously herewith.

presence of nitrosamines. Ex. G,[2] Clevenger Rpt., 6-10. Plaintiffs likewise mischaracterize his opinion by asserting that "Dr. Clevenger makes the unsupported and illogical leap that just because the USP monograph doesn't specifically state that valsartan should be tested for nitrosamines, that nitrosamine contaminated valsartan is considered pharmaceutically equivalent to the reference-listed drug ('RLD')." Mot., 3-4. This characterization is demonstrably false.

As to pharmaceutical equivalence, Dr. Clevenger explained that it requires compliance with the applicable USP monographs for the RLD for valsartan containing products. He opined that Aurobindo's finished drug products ("FD") "met the identical compendial standard . . . to be considered pharmaceutically equivalent to the" RLD. Ex. G, Clevenger Rpt., 8 (footnote omitted). He also explained that the USP did not specifically require testing for nitrosamines (which Plaintiffs cannot dispute) and permitted impurities (found in all pharmaceutical products) up to the levels identified in the monograph. *See* Mot., 4 ("[T]he USP monograph itself doesn't specifically direct companies to test their valsartan for nitrosamines."); *see also* Ex. B, Najafi Tr. 188:15-188:25 (explaining how USP's test cannot identify nitrosamine impurities since nitrosamines are invisible to the UV

[2] Exhibits F and G references exhibits that Plaintiffs filed with their Opposition to Defendants' Motion to Compel Production of Testing and Other Materials in the Possession of Class Expert, Dr. Ron Najafi on April 25, 2022, ECF No. 2023. Exhibit B references exhibit that Defendants filed with their Joint Motion to Exclude the Opinions of Ron Najafi, Ph.D. on May 3, 2022, ECF No. 2033.

detector). Dr. Clevenger also confirmed that the level of nitrosamine impurities in Aurobindo's FD did not exceed the permitted level of impurities in the monographs. Ex. F, Clevenger Tr. 70:11-71:1.

Separately, Dr. Clevenger opined that the alleged presence of nitrosamines would not be expected to interfere with the bioequivalence of the Active Pharmaceutical Ingredient ("API"). Ex. G, Clevenger Rpt., 6; *see also* Ex. F, Clevenger Tr. 63:7-63:12. That is, he opined that there is no evidence that the nitrosamines caused a "significant difference in the rate and extent to which [valsartan] . . . becomes available at the site of drug action." Ex. G, Clevenger Rpt., 6 (citation omitted).

Plaintiffs also fault Dr. Clevenger and seek to exclude his bioequivalency opinion because he did not read a particular USP webpage stating that manufacturers should "identify[] and prevent[] the presence of unacceptable impurities" and that "USP is supporting manufacturers and regulators with tools and solutions for testing, assessing risk and understanding potential sources related to nitrosamine impurities." Mot., 4 (emphasis omitted). Setting aside that the USP monographs did not contain that information, USP did not publish that webpage until 2020—nearly ***two years*** after Aurobindo manufactured and distributed its FD. As a result, Plaintiffs are simply wrong that "there has always been a requirement to prevent 'unacceptable impurities' built into the USP description of [V]alsartan's

specifications." Mot., 4. Further, Plaintiffs ignore that the FDA itself determined that the presence of nitrosamines was "unexpected" and published guidance in 2018 that established Acceptable Intake ("AI") Levels for nitrosamines and advised that patients should continue taking their VCDs, even if they contain nitrosamines, until speaking with their healthcare providers. FDA, *FDA Announces Voluntary Recall of Several Medicines Containing Valsartan Following Detection of an Impurity* (July 13, 2018), https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity.

Plaintiffs are also wrong in asserting that Dr. Clevenger "conceded that the USP prohibited NDMA and NDEA in valsartan." Mot., 4-5. He gave no such testimony. The USP web page is not a monograph and simply advises that USP can provide "tools and solutions" to assess risk in the future. Furthermore, even today, the most current monographs for VCDs do not mention nitrosamines. Lastly, Dr. Clevenger correctly explained that cGMP practices are relevant to potential contamination ("cross-contamination is also dealt with in the GMP world"), but he did not express any cGMP opinions, which are outside the scope of his report. Mot., 5 (citing Ex. F, Clevenger Tr. 73:9-22).

At bottom, Plaintiffs ask this Court to exclude Dr. Clevenger on the basis of their own makeshift versions of his opinions and some language that appeared on

the internet years after Aurobindo distributed the pertinent FDs. These arguments should be rejected, as they present no legitimate basis for exclusion.

B. Dr. Clevenger's Opinion Concerning Aurobindo's ANDA Is Not A "Net Opinion."

[redacted]

[redacted]

[redacted]

3 [redacted]

[redacted]

C. Dr. Clevenger's Volatilization Opinion Is Reliable.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted] [redacted]

4 [redacted]

[redacted]

[redacted]

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5 [redacted]

[redacted]

IV. CONCLUSION

There is no basis upon which to grant Plaintiffs' Motion. It must be denied.

Dated: June 2, 2022

Respectfully submitted,
By: */s/.John K. Gisleson*

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